

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

Davies Collison Cave
GPO Box 3876
SYDNEY NSW 2001

DCC (Sydney)
Mail Rcvd

23 AUG 2004

ARNO processed by *vm*
on *23.08.04*
Action *msc DC*

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 20 AUG 2004

Applicant's or agent's file reference
12262441

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/AU2004/000798

International filing date (day/month/year)
18 June 2004

Priority date (day/month/year)
20 June 2003

International Patent Classification (IPC) or both national classification and IPC

Cl. 7 C07K 14/62, C07K 14/64, C07K 14/65, C07K 14/575, A61K 38/22, A61K 38/28, A61K 38/30, A61P 3/10, A61P 15/00, A61P 15/08, A61P 15/14, A61P 19/00, A61P 35/00

Applicant

HOWARD FLOREY INSTITUTE OF EXPERIMENTAL PHYSIOLOGY & MEDICINE et al

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaustalia.gov.au
Facsimile No. (02) 6285 3929

Authorized Officer

DAVID GRIFFITHS

Telephone No. (02) 6283 2628

BEST AVAILABLE COPY

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2004/000798

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☒ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☒ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

BEST AVAILABLE COPY

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2004/000798

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

BEST AVAILABLE COPY

1. Statement

Novelty (N)	Claims 1 - 49	YES
	Claims	NO
Inventive step (IS)	Claims 1 - 49	YES
	Claims	NO
Industrial applicability (IA)	Claims 1 - 49	YES
	Claims	NO

2. Citations and explanations:

The present application relates to monomeric cyclic analogues of the B-chain of relaxin superfamily proteins that bind to a biological target of the relaxin superfamily protein and modulate the activity of the target. Methods of making the analogues and their uses are also claimed.

This opinion is based on the following citations:

D1. *International Journal of Peptide & Protein Research* (1982), 20(3), 207-17;

D2. *Chem. Pept. Proteins, Proc. USSR-FRG Symp., 3rd* (1982), Meeting Date 1980, 327-35;

D3. *Doklady Bolgarskoi Akademii Nauk* (1976), 29(11), 1641-4.

Documents D1 and D2 disclose cyclic insulin B-chain derivatives for use in semi-synthesis; D3 discloses, amongst other things, a dithiolated cross-linked cyclic monomer of the insulin B-chain in the context of structure elucidation. None of the citations discloses the derivatives binding to biological targets to result in biological activity. The present claims must therefore be acknowledged as being novel and inventive over the citations.

All claims meet the criterion of being industrially applicable.